

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 28 DEC 2005

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Applicant's or agent's file reference	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/CA2004/001659	International filing date (day/month/year) 21 September 2004 (21-09-2004)	Priority date (day/month/year) 23 September 2003 (23-09-2003)	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 7/48, A61K 9/06, A61K 35/78, A61P 17/00			
Applicant ORIGIN BIOMEDICINALS INC. ET AL			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 2 sheets, as follows:</p> <p style="padding-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="padding-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. 1 and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) ,containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 20 April 2005 (20-04-2005)		Date of completion of this report 20 December 2005 (20-12-2005)	
Name and mailing address of the IPEA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001(819)953-2476		Authorized officer Ingrid Elder (819) 934-2327	

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Box No. I Basis of the report

1. With regard to the language, this report is based on:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
 - ☐ international search (Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (Rule 12.4(a))
 - ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
 - ☐ the international application as originally filed/furnished
 - ☒ the description:
 - ☒ pages 1-9 as originally filed/furnished
 - ☐ pages* received by this Authority on 13 January 2005 (13.01.05)
 - ☐ pages* received by this Authority on _____
 - ☒ the claims:
 - ☐ pages as originally filed/furnished
 - ☐ pages* as amended (together with any statement) under Article 19
 - ☒ pages* 10-11 received by this Authority on 20 April 2005 (20.04.05)
 - ☐ pages* received by this Authority on _____
 - ☒ the drawings:
 - ☒ pages 1/1 as originally filed/furnished
 - ☐ pages* received by this Authority on _____
 - ☐ pages* received by this Authority on _____
 - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☒ The amendments have resulted in the cancellation of:
 - ☐ the description, pages _____
 - ☒ the claims, Nos. 11-17
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - ☐ the description, pages _____
 - ☐ the claims, Nos. _____
 - ☐ the drawings, sheets/figs _____
 - ☐ the sequence listing (*specify*): _____
 - ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-11</u>	YES
	Claims	<u>none</u>	NO
Inventive step (IS)	Claims	<u>1-11</u>	YES
	Claims	<u>none</u>	NO
Industrial applicability (IA)	Claims	<u>1-11</u>	YES
	Claims	<u>none</u>	NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1: US 6 150 422
D2: EP 0 755 673
D3: CA 2 353 071
D4: US 5 665 367
D5: CA 2 215 210
D6: CA 2 221 236

Novelty

D1 discloses a stable gelled composition in the form of a cream, an ointment or a paste, wherein said composition contains at least one lipophilic polyphenol active agent sensitive to oxygen and/or to water, such as flavonoids; a gelling agent, such as a gum; and a solvent, such as vegetable oils. D1 also discloses that the oily gel comprising the lipophilic agent is stable for prolonged storage use.

D2 discloses a stable topical application containing at least one water-sensitive active agent, such as green tea extract; a polyol, such as glycerol or glycols; and a vegetable oil, such as jojoba oil. D2 also discloses that the polyol in combination with the structuring agent (aka oil) prevents the degradation of the water-sensitive actives.

D3 discloses a topical composition comprising an active agent, such as dithranol; an oil body from plant cells, such as coconut oil and jojoba oil; and a gelling agent, such as cellulose and gums (page 16, lines7-13).

D4 discloses a skin conditioning composition comprising a flavonoid, a retinol and a cosmetically acceptable vehicle. Example 10 discloses a non-aqueous skin care composition comprising a gum and herbal oils.

D5 and D6 disclose the incorporation of polyphenol extractions from tea (*Camellia sinensis*) and green tea into topical compositions.

The subject-matter of the Application is novel over D1-D6 in that the an adsorbent binding carrier to which a polyphenol is adsorbed is not disclosed in any of D1-D6.

Claims 1-11 are considered to be novel and therefore comply with Article 33(2) of the PCT.

(See Supplemental Box)

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Inventive Step

The problem underlying the invention is to devise a means by which polyphenols can be evenly disbursed in anhydrous topical mixtures in order to provide polyphenol stability while providing suitable commercial appeal to a topical product and which will not inhibit the ability of the polyphenols to be released on and into the aqueous environment of the skin when topically applied.

This problem has been solved by the use of an inert adsorbent binding carrier and can be seen from the test results on pages 7-8 of the present Application.

This solution is considered surprising in light of D1-D6, which gave no indication as to how the improved properties were to be achieved, and so an inventive step can be acknowledged.

Claims 1-11 therefore comply with Article 33(3) of the PCT.

Industrial Applicability

The subject matter of claims 1-11 is considered to be industrially applicable and complies with Article 33(4) of the PCT since an anhydrous topical composition which evenly disburses polyphenols through the use of an inert adsorbent binding carrier is disclosed.

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We claim;

1. A composition of matter comprising an adsorbent binding carrier and a polyphenol in an anhydrous mixture, wherein said polyphenol is adsorbed to said binding carrier.
2. The composition according to claim 1 additionally comprising an anhydrous topical cream, gel or ointment, wherein the polyphenol adsorbed to said binding carrier is evenly disbursed within the cream, gel or ointment, and wherein said polyphenol will be released on and into the skin when the cream, gel or ointment is applied thereto.
3. The composition according to claim 2, wherein the polyphenol comprises polyphenols derived from tea (*Camellia sinensis*) or green tea.
4. The composition according to claim 2, wherein the binding carrier is selected from the group consisting of talcs and clays, alginates, algae, agars, gums, gelatins, celluloses, silica, silica gels, simethicone, salicylates, silicates and silicone resins, tragacanth, calcium carbonates and magnesium and zinc oxides.
5. The composition according to claim 4, wherein the binding carrier is silica or a silica gel.
6. The composition according to claim 4, wherein the binding carrier is a salicylate or a silicate.
7. The composition according to claim 4, wherein the binding is a magnesium or zinc oxide.
8. The composition according to claim 2, wherein the anhydrous topical cream, gel or ointment comprises saturated or unsaturated plant oils or waxes.
9. The composition according to claim 8, wherein the oils or waxes are natural plant oils or waxes.
10. The composition according to claim 9, wherein said natural plant oils or waxes are shea butter, Aloe vera, almond oil, olive oil, avocado oil, coconut oil, jojoba oil or Avena sativa

oil.

11. A method of formulating a composition according to any one of claims 1 – 10 comprising the steps of:

- a. triturating an adsorbent binding carrier with a polyphenol until uniform; and
- b. subsequently adding an anhydrous topical cream, gel or ointment base.

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